



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/813,904	03/31/2004	Iain H. Kalfas	101896-366 (DEP5181)	5037

21125 7590 04/20/2009
NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER

YANG, ANDREW

ART UNIT	PAPER NUMBER
----------	--------------

3775

NOTIFICATION DATE	DELIVERY MODE
-------------------	---------------

04/20/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/813,904	Applicant(s) KALFAS ET AL.	
	Examiner ANDREW YANG	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-35,56,57 and 59-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-35,56,57 and 59-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments, see Pre-Brief Conference, filed 11/20/2008, with respect to the rejection(s) of claim(s) 1, 56, and 60 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Montague et al and Cavagna et al.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

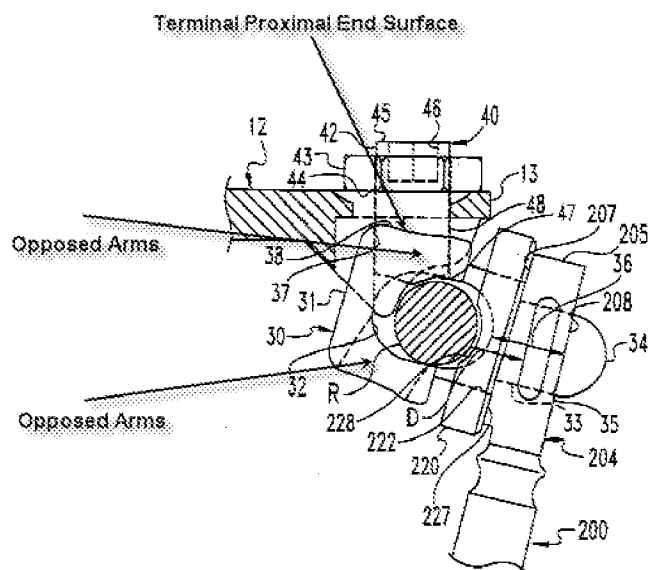
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-12, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Montague et al. (U.S. Patent No. 5688272).

Montague et al. discloses a spinal fixation system having two bone anchors 200 having bone engaging portions and rod receiving portions 30. Each rod receiving portion can be considered to have opposed arms having a proximal terminal end surface as pictured on the next page. A rod R is disposable between the opposed arms and a connecting plate 10 has a distal surface that bears against the proximal terminal end surface of the opposed arms (Column 7, Lines 50-51). A set screw 40 threadably

engages the rod receiving portion via hole 37 and fixes the rod to the bone anchor 200.

A cap 43 is threadably engaged with the set screw 40, via a bore in the cap 30, such that the cap 43 fixes the plate 10 to the rod receiving portion 30. The connecting plate 10 defines an opening 18 at an end and a spanning portion 11 extending therefrom. The set screw extends through the opening 18. The connecting plate includes a buttress 14 at a distal side of the spanning portion 11. A set of anchors are connected by a rod, and a set of anchors are connected by the connecting plate 10.



The connecting plate has a distal bearing surface 16 that is domed and can be considered partially spherical. As seen in figure 10, the cap has a distal bearing surface that is domed that mates with a proximal bearing surface of the connecting plate.

Claims 1, 4, 17-20, 29, 56, 59, and 60-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Cavagna et al. (WO 01/47425).

Cavagna et al. discloses a spinal fixation system having at least two bone anchors 1 having a bone engaging portion 2 and a rod receiving portion 4 having apposed arms 6, 7. A rod 50 is disposable between the opposed arms of the rod receiving portions of at least two bone anchors. A connecting plate 28 has a distal surface that bears against a proximal terminal end surface of the opposed arms of the rod receiving portion (Figure 5). A set screw 53 threaded engages the rod receiving portion and fixes the rod to the bone anchor. The connecting plate 28 is oriented at an angle in the range of about 20-160 degrees or between 60-120 degrees relative to the rod (Figure 12). The connecting plate defines an opening for receiving screw 29 at an end and a spanning portion (Figure 5, 12). Each end of the connecting plate 28 is fixed to a proximal surface of a bone anchor. The bone anchors are monoaxial.

In regard to claims 56 and 59, the spinal fixation system has at least two sets of bone anchors each bone anchor having a bone engaging portion and a receiving portion (Figure 12). A fixation element 50 is disposable between the opposed arms of the receiving portions of the first set of bone anchors. A connecting plate 28 connects a bone anchor of the first set with a bone anchor of the second set. The connecting plate 28 has a distal surface that bears against a proximal terminal end surface of the opposed arms of the receiving portion of the first set. A closure mechanism extends through the connecting plate and engages the bone anchor. The closure mechanism is a threaded rod which is engaged with a cap to form member 29. It is considered once

Art Unit: 3775

the plate is connected the rod 50 is unable to move out of the channel and thus the rod is fixed in the receiving portion.

With reference to Figure 12, the use of the device is as follows; first and second bone anchors are implanted into first and second vertebra and connected with a rod 50. The distal surface of a connecting plate is positioned on a proximal terminal end surface of opposed arms of a rod receiving portion. A closure mechanism 29 is extended through the connecting plate to engage the rod receiving portion. Third and fourth bone anchors are implanted into the first and second vertebra and on an opposite side of the spine of the first and second bone anchors, respectively. A connecting plate is coupled between the first and third bone anchors and between the second and fourth bone anchors.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over

Montague et al. (U.S. Patent No. 5688272).

Montague et al. discloses the set screw and cap threadably mated via a bore in the cap however fails to disclose the cap threadably engaging the set screw via a bore in the set screw. It would have been obvious to one having ordinary skill in the art at the

Art Unit: 3775

time the invention was made to have a cap that engages a threaded bore defined by the set screw, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Montague et al. (U.S. Patent No. 5688272) in view of Small et al. (U.S. Patent No. 5129899). Bono et al. (U.S. Patent No. 2004/0087949).

Montague et al. disclose the claimed invention except for a floating washer with a bearing surface that mates with the distal bearing surface of the cap, and rails that slidably engage the connecting plate. Small et al. teaches a bone plate 17 having an elongated hole 20 and a washer 35. The washer mates with a distal bearing surface 32 of a nut 31 and has rails 37, 38 that slideably engages the plate 17. The connecting plate is fixed to the bone anchor 11 by compression between the floating washer 35 and the bone anchor 11. The washer allows the device to be placed anatomically with little manipulation (Column 2, Lines 66-67 and Column 3, Lines 1-2). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Montague et al. with a floating washer with a bearing surface that mates with the distal bearing surface of the cap, and rails that slidably engage the connecting plate in view of Small et al. so that the cap and set screw could be place anatomically with little manipulation.

Claims 21-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Cavagna et al. (WO 01/47425) in view of Dove et al. (U.S. Patent No. 5366455).

Cavagna et al. disclose the claimed invention except for a plate that has a spanning member that is arcuate in shape and a hole that is circular or elliptical in shape. Dove et al teaches a spinal fixation device with bone anchors 29, a rod 26, and a plate 10. The plate has a spanning portion 11 that is curved and is also offset from a plane defined by the end 13 of the plate 10 to allow clearance for the spinous processes (Column 2, Lines 62-65) and a hole 14 that is substantially elliptical (Figure 2) to receive a screw (Column 2, Lines 42-44). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Cavagna et al. with a curved spanning portion and an elliptical hole in view of Dove et al. so that the plate will have clearance for the spinous processes and to receive screws..

With regard to the radius of curvature and the distance that the spanning portion is offset from the end of the plate, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the spanning portion of Cavagna et al. as modified by Dove et al. with a radius of curvature between 8mm and 12mm or 5mm and 15mm and offset at least 3mm and between about 5mm and 10mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Deleted: curvature

Claims 30-35 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cavagna et al. (WO 01/47425) in view of Mathis et al. (U.S. Publication No. 2004/0186474).

Cavagna et al. disclose the claimed invention except for using polyaxial screws that have a radius of curvature about a point which the bone screw pivots for the bone anchors. Mathis et al. teaches an implant for use in spinal surgery that uses a polyaxial screw with a spherical head 2, held in rod receiving portion 3. The head has a radius of curvature about a point which the bone screw pivots. The use of the polyaxial screw is so that the angular position of the screw can be changed relative to the receiver portion 3 (Paragraph 38). It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Cavagna et al. with bone anchors that are polyaxial screws in view of Mathis et al. so that the angular position of the bone anchors could be adjusted.

With regard to claim 35, Mathis et al. teaches a compression element 10 for fixation of the angular position of the polyaxial screw. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Cavagna et al. with a polyaxial screw with a compression member in view of Mathis et al. so that the angular position could be fixed.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cavagna et al. (WO 01/47425) in view of Pisharodi (U.S. Patent No. 6355038).

Cavagna et al. disclose the claimed invention except for the opening of the connecting plate being open ended. Pisharodi teaches a spinal fixation assembly with a

Art Unit: 3775

plate 32 having an open-ended hole 44 for facilitating assemble of the plate 32 to screws 34. It would have been obvious to one skilled in the art at the time the invention was made to construct the device of Cavagna et al.. with a plate having a hole with an open end in view of Pisharodi in order to facilitate assemble of the plate to the bone anchors.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW YANG whose telephone number is (571)272-3472. The examiner can normally be reached on IFP.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on (571)272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/813,904
Art Unit: 3775

Page 10

/Andrew Yang/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775